

- 1 1. (Original) An oral solid composition of nateglinide comprising:
  - 2 a) nateglinide or pharmaceutically acceptable salts thereof; and
  - 3 b) at least one pharmaceutically acceptable surfactant,
- 1 2. (Original) The oral solid composition of claim 1, wherein the nateglinide comprises  
2 an amount of from about 5% w/w to about 70% w/w of the composition.
- 1 3. (Original) The oral solid composition of claim 1, wherein the surfactant comprises  
2 one or more of anionic, nonionic, cationic, and mixtures thereof.
- 1 4. (Original) The oral solid composition of claim 3, wherein the anionic surfactants  
2 comprises one or more of sodium lauryl sulphate, potassium dodecyl sulphonate, sodium  
3 dodecyl benzene sulphonate, sodium salt of lauryl polyoxyethylene sulphate, lauryl  
4 polyethylene oxide sulfonate, dioctyl ester of sodium sulphosuccinic acid or sodium lauryl  
5 sulphonate, and mixtures thereof.
- 1 5. (Original) The oral solid composition of claim 4, wherein the surfactant is sodium  
2 lauryl sulphate.
- 1 6. (Original) The oral solid composition of claim 3, wherein the nonionic surfactants  
2 comprises one or more of polysorbate 80, nonyl phenol polyoxyethylene ether, tridecyl  
3 alcohol polyoxyethylene ether, dodecyl mercaptan polyoxyethylene thioether, the lauric ester  
4 of polyethylene glycol, the lauric ester of sorbitan polyoxyethylene ether or tertiary alkyl  
5 amine oxide, and mixtures thereof.
- 1 7. (Original) The oral solid composition of claim 6, wherein the surfactant is polysorbate  
2 80.
- 1 8. (Original) The oral solid composition of claim 3, wherein the cationic surfactants  
2 comprises one or more of distearyl dimethyl ammonium chloride, stearyl dimethyl benzyl  
3 ammonium chloride, stearyl trimethyl ammonium chloride, coco dimethyl benzyl ammonium  
4 chloride, dicoco dimethyl ammonium chloride, cetyl pyridinium chloride, cetyl trimethyl  
5 ammonium bromide, stearyl amine salts that are soluble in water such as stearyl amine acetate  
6 and stearyl amine hydrochloride, stearyl dimethyl amine hydrochloride, distearyl amine  
7 hydrochloride, alkyl phenoxyethoxyethyl dimethyl ammonium chloride, decyl pyridinium

8 bromide, pyridinium chloride derivative of the acetyl amino ethyl esters of lauric acid, lauryl  
9 trimethyl ammonium chloride, decyl amine acetate, lauryl dimethyl ethyl ammonium  
10 chloride, the lactic acid and citric acid and other acid salts of stearyl-1-amidoimidazoline with  
11 methyl chloride, benzyl chloride, chloroacetic acid and similar compounds, and mixtures  
12 thereof.

1 9. (Original) The oral solid composition of claim 1, wherein the surfactant comprises an  
2 amount of from about 0.5% w/w to about 10% w/w of the composition.

1 10. (Original) The oral solid composition of claim 1, wherein the composition further  
2 comprises one or more pharmaceutically acceptable excipients comprising fillers, binders,  
3 disintegrants, lubricants, glidants, coloring agents, flavoring agents, and coatings.

1 11. (Original) The oral solid composition of claim 10, wherein the filler comprises one or  
2 more of corn starch, lactose, white sugar, sucrose, sugar compressible, sugar confectioners,  
3 glucose, sorbitol, calcium carbonate, calcium phosphate-dibasic, calcium phosphate-tribasic,  
4 calcium sulfate, microcrystalline cellulose, silicified microcrystalline cellulose, cellulose  
5 powdered, dextrates, dextrins, dextrose, fructose, kaolin, lactitol, mannitol, sorbitol, starch,  
6 starch pregelatinized, sucrose, and mixtures thereof.

1 12 – 13 (Cancelled)

1 14. (Original) The oral solid composition of claim 10, wherein the binder comprises one  
2 or more of methyl cellulose, hydroxypropyl cellulose, polyvinylpyrrolidone, gelatin, gum  
3 arabic, ethyl cellulose, polyvinyl alcohol, pullulan, pregelatinized starch, agar, tragacanth,  
4 sodium alginate, propylene glycol, and mixtures thereof.

1 15. (Cancelled).

1 16. (Original) The oral solid composition of claim 10, wherein the disintegrant comprises  
2 one or more of starch, croscarmellose sodium, crospovidone, sodium starch glycolate, and  
3 mixtures thereof.

1 17. (Cancelled)

- 1 18. (Original) The oral solid composition of claim 10, wherein the lubricant comprises  
2 one or more of colloidal anhydrous silica, stearic acid, magnesium stearate, calcium stearate,  
3 talc, hydrogenated castor oil, sucrose esters of fatty acids, microcrystalline wax, yellow  
4 beeswax, white beeswax, and mixtures thereof.
- 1 19. (Cancelled)
- 1 20. (Original) The oral solid composition of claim 1, further comprising at least one other  
2 anti-diabetic compound.
- 1 21. (Original) The oral solid composition of claim 20, wherein the antidiabetic compound  
2 comprises glitazones, sulfonyl urea derivatives and metformin, either in free form or in form  
3 of a pharmaceutically acceptable salt thereof.
- 1 22. (Original) The oral solid composition of claim 1, wherein the composition comprises  
2 one or more of powder, tablets, granules, pellets, spheroids, caplets and capsules.
- 1 23 - 32. (Cancelled)
- 1 33. (Original) A process for the preparation of a pharmaceutical composition of  
2 nateglinide, the process comprising the steps of:
  - 3 i. blending nateglinide or pharmaceutically acceptable salts thereof,  
4 surfactant and one or more pharmaceutically acceptable excipients;  
5 and;
  - 6 ii. processing into a solid dosage form.
- 1 34. (Original) The process of claim 33, wherein the blend of step a) is granulated.
- 1 35. (Original) The process of claim 34, wherein the granulation is carried out by a wet  
2 granulation or a dry granulation technique.
- 1 36. (Cancelled)
- 1 37. (Currently Amended) The process of claim 36 35, wherein the wet granulation is  
2 carried out using a granulating fluid comprising one or more of methylene chloride, isopropyl  
3 alcohol, acetone, methanol, ethanol, water, and mixtures thereof.

1 38. (Cancelled)

1 39. (Currently Amended) The process of claim 38 35, wherein the dry granulation is  
2 carried out by slugging or roller compaction.

1 40. (Cancelled)

1 41. (Original) The process of claim 33, further comprising mixing at least one other  
2 antidiabetic compound.

1 42. (Original) The process of claim 41, wherein the antidiabetic compound comprises one  
2 or more of glitazones, sulfonyl urea derivatives and metformin, either in free form or in form  
3 of a pharmaceutically acceptable salt.

1 43. (Original) The process of claim 33, wherein the dosage form comprises one or more  
2 of powder, tablets, granules, pellets, spheroids, caplets and capsules.

1 45 - 46 (Cancelled)

1 47. (Original) A process for preparation of oral tablets of nateglinide, the process  
2 comprising blending nateglinide, surfactant, filler, disintegrant, binder and lubricant; and  
3 compressing.

1 48. (Original) A method for the prevention or treatment of metabolic disorders, type 2  
2 diabetes mellitus, or a disease or condition associated with diabetes mellitus, the method  
3 comprising administering to a patient in need thereof a pharmaceutical composition  
4 comprising nateglinide or pharmaceutically acceptable salts thereof; and at least one  
5 pharmaceutically acceptable surfactant.